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FROM PUNISHMENT TO PREVENTION?

Medical Errors Reported in Sweden in 1989 and 1993

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ABSTRACT

This study describes the Swedish self-reporting system for serious injuries caused by medical treatment, how the authorities handle cases reported by health care providers, and how this influences the willingness to report medical errors. The focus shifted from punishment to prevention when the state authority was reorganised in 1991. The present study was performed in order to identify whether there was a change in reporting medical errors between 1989 and 1993. There was a great increase in the number of reported cases, and the manner of handling lex Maria changed during that period. Cases forwarded for disciplinary action decreased from 35 to 5% of reported cases. There was also a change in the categories of personnel reported, with an increase for medical doctors and a decrease for nurses. Employees with organisational responsibility were not reported to a greater extent than earlier. One of the major problems with the Swedish lex Maria system still remains, since the National Board of Health and Welfare retains the duty to report to the Medical Responsibility Board. The question can be posed as to whether the present self-reporting system, which is run by a state authority with the duty to forward reports for disciplinary action, really contributes to improved patient safety.

INTRODUCTION

This study describes how Swedish authorities handle medical errors reported by health care providers, and also describes effects on the willingness to report medical errors. The Swedish self-reporting system for medical errors focuses on serious injuries caused by treatment in the health care sector and has its origin in an incident that occurred in 1936 at the Maria Hospital in Stockholm (Ödegård and Löfroth, 1996). Four patients died following injection of mercuric oxicyanide instead of a local anesthetic. The first law in 1937 focused on disciplinary action, assigning the duty to report patient injuries to both the National Board of Health and Welfare (NBHW) and the police. The regulation (called lex Maria) has been changed over the past 60 years, as has the manner in which the NBHW handles lex Maria cases. The focus has changed from having a disciplinary aim, where the issue was to determine guilt, to the aim of prevention. In connection with a reorganization of the NBHW in 1991, a variety of measures were adopted in order to widen the scope of prevention in the area of patient injuries caused by medical treatment. Extensive information was distributed to health care personnel in order to achieve a better understanding of the importance of reporting medical errors.

In this report the phrase “medical error” is used, but it is important to be aware of the fact that a reported lex Maria case does not necessarily have to involve an error. It can involve an injury that was impossible to avoid. Every serious patient injury, or even the risk of serious injury, caused by medical treatment should be defined as a lex Maria case.

BACKGROUND

There are several reasons for examining medical errors in the health care sector. One of the most important issues is to obtain information about primary causes in order to develop activities that can prevent the recurrence of similar mistakes (Vincent, Audley and Ennis, 1993). By their very nature, medical errors are costly in both human and financial terms. However, some obstacles exist with respect to reporting medical errors. One is the medical culture, where "error-free practice" is the aim, and others are the fear of litigation and the lack of definitions concerning the scope and nature of the problem (Leape, 1994). An additional reason is that these events are not only traumatic for the patients and their relatives, but also for the health care staff who have been involved in the events. Anger, distress, and feeling personally attacked are common responses to litigation (Bark et al., 1997).

Reducing the number of medical errors is a frequently discussed subject in professional medical journals and even over the web (Leape, 1997). The growing openness regarding mishaps with patients has led to an increasing number of partnerships between human factor specialists and doctors (Bogner, 1994; Reason, 1997; Svensson, 1997). The understanding of human error and how multiple latent failures lie behind accidents can contribute to knowledge concerning the nature of an accident.

Within the health care sector, an incorrect judgment in one simple operation or a stressful situation that disturbs concentration for a split second can have serious consequences for the patient. However, risks within the health care sector are not only associated with individual events or medical equipment. There are frequently deficiencies with respect to organizational structures, procedures and processes, and with respect to resources for implementing quality management (Rasmussen, 1997). Ambiguity regarding the responsibilities of several occupational groups, or regarding different activities, or in relation to other units and areas of responsibility, can also be related to risks (Larsson and Ödegård, 1993). The role of organizational factors in the genesis of accidents has been analyzed and discussed by Reason (1991, 1997) and Rasmussen (1997) from the perspective of health care organization.

National information systems and procedures concerning medical errors in Sweden

There are three different reporting systems in Sweden at the national level that can provide information concerning medical errors (Figure 1).

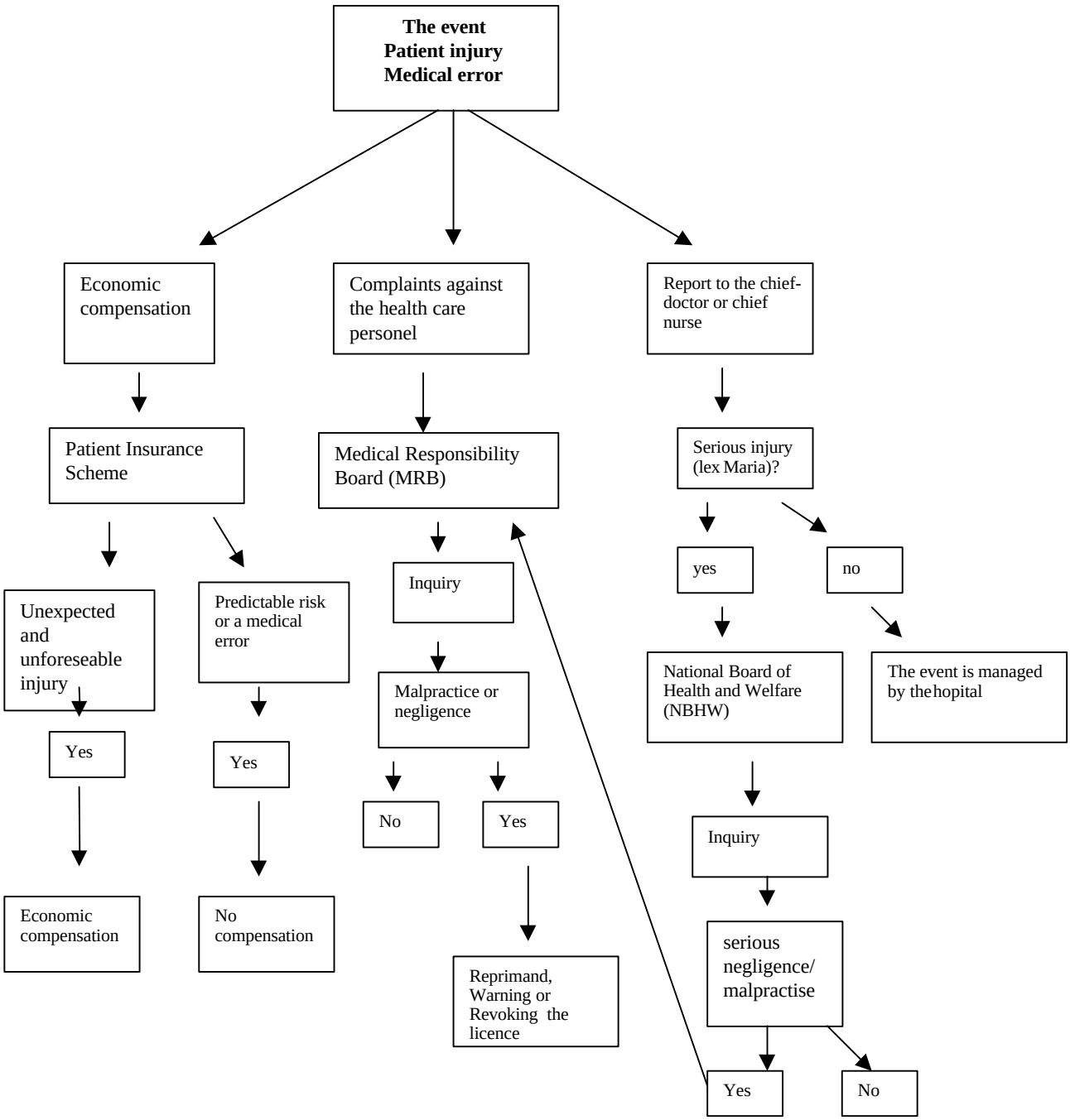

Figure 1 Flow chart of the national information systems for medical errors in Sweden.

The Patient Insurance System. Through the patient insurance system a patient can report an injury caused by treatment, and receive economic compensation whether or not malpractice has taken place. The insurance plan does not compensate all medical injuries, but is instead limited to those that are unexpected and unforeseeable or improbable in the judgment of the attending physician. If an injury is a predictable result or risk of a medical encounter, it is generally not compensable (Oldertz, 1984).

The Medical Responsibility Board (MRB). This authority receives complaints against doctors, nurses, dentists and other health-related personnel. It is a freestanding authority that can be compared to a civil court for medical issues (Rosenthal, 1988). Patients can report directly to the MRB, which investigates whether the accused individual has been negligent or has given substandard care. Many of the claims submitted to this authority are the result of poor communication and misunderstanding among the health care staff, primarily doctors, and the patients. The Board can give health care providers a reprimand, a warning, or revoke their license to practice. The NBHW can also report cases for disciplinary review to this Board.

The National Board of Health and Welfare (NBHW). If a patient becomes seriously injured or ill while receiving medical treatment or services, even if there was a serious risk of injury, it is the duty of the health care staff to report the event to the NBHW. This regulation is called lex Maria, and it is a self-reporting system with preventive purposes. The inquiries can lead to criticism of an individual or manager, as well as to demands for changes in routines. Secondly, if the Board finds that an individual has made a serious mistake (negligence or malpractice), it can forward the report to the MRB for disciplinary review. This means then that the state authority must deal both with prevention and with sanctions. The NBHW is the primary medical supervisory authority, and its overall purpose is to foster quality and safety in the health care sector.

Regulations - Historical background

Two events have had particular influence on the debate concerning the legal system for dealing with medical errors in Sweden. The first, which took place in 1936 at the Maria Hospital in Stockholm, resulted in the first regulation, lex Maria, which was enacted in 1937 (Ödegård and Löfroth, 1996). The second event occurred in 1983. Three patients died and 12 were in mortal danger following dialysis treatment at the Linköping University hospital. In spite of the fact that the lex Maria regulation had been changed in 1982 and now had prevention as its purpose instead of its previous disciplinary focus, where the issue was to determine guilt, the investigation nevertheless focused on the person at the end of the series of events that contributed to the adverse event. A hospital nurse was found guilty of manslaughter and endangerment of life. This accident was followed by extensive debate concerning the legal system and the need for a "scapegoat", which had dominated the inquiries.

In connection with a reorganization of the NBHW in 1991, changes were made in the way lex Maria cases were handled. The ambition was to increase the willingness of health care staff to report medical errors in order to obtain a better base for activities aimed at prevention. A variety of methods were adopted in order to broaden the scope of prevention in the area of patient safety.

One of the activities initiated to help achieve this new purpose was the Risk Data Base project (Ödegård, 1995a). The purpose of the project was to collect and structure the experiences from cases of medical errors (lex Maria) and to improve the potential for risk identification in order to reduce or eliminate risk before injuries occurred. A computerized information-system was developed containing information about lex Maria cases reported since 1992 and suggesting preventive actions. The information in the Risk Data Base is anonymous with respect to both hospitals and individuals. The argument was that there was no need for identification in order to achieve preventive objectives. Another reason was that identifying a hospital or an individual could have negative effects on the willingness of health care staff to report medical errors. The purpose was to improve the potential for a systematic risk appraisal and to inform health care providers about discovered risks.

Another activity was "RiskRonden" (1992), an information pamphlet issued periodically that highlights a single injury or incident by describing and analyzing it in detail. The dual purpose of the pamphlet was to stimulate debate on safety and to encourage health care staff to report medical errors. The pamphlet was targeted at special groups e.g. chief physicians or ward managers, depending on the type of incident being reported.

An additional part of the Risk Data Base project was "Risk Analyses and Patient Safety", a project in which critical incidents associated with medical errors that occurred on hospital wards were collected. Critical incidents were collected into risk scenarios as described by the staff and compared with the reports compiled in the RDB. This information was also reported back to the ward staff and managers with the aim of upgrading and specifying local safety routines.

The most important overall purpose of these activities was to shift the focus from the sole aim of blaming a particular person to more constructive actions aimed at reducing or eliminating risks for patient injuries. At the same time, employees managing lex Maria cases at the NBHW were introduced to a new approach for investigating medical errors. This was done in a three-day course organized in collaboration with the nuclear power industry and focusing on Man, Technology and Organizational analyses (Bento, 1992).

Extensive information was provided about the advantages of reporting lex Maria cases in order to avoid similar errors in the future (Ödegård, 1995 b). Information given to health care professionals emphasized

the fact that medical errors are often due to system failures rather than individual shortcomings. It was pointed out that the disciplinary focus in the management of medical errors and incidents should be changed to a focus on prevention. This also involved a change in the criteria for submitting cases to the MRB. Another ambition in dealing with these issues was to focus on clinical department heads and their responsibilities for their departments. It was pointed out that when analyzing medical errors, the issues of most importance should be guidelines, routines, local regulations, organizational structures and the introduction of new employees. The focus on responsibility should target clinical department heads when medical errors are being analyzed. However, an association still remained between the lex Maria reporting system and disciplinary action. If it was found in the investigation that an individual had been negligent or provided substandard care, the authority would propose disciplinary action and forward the report to the MRB.

The starting point for this study was the new regulation and the new way of handling reported medical errors (lex Maria) at the NBHW. The study examines whether the intended purpose of changing the focus from punishment to prevention has influenced the willingness to report lex Maria cases. The study period was from 1989 to 1993 in order to compare the situation before and after 1991, when most changes were introduced. The underlying questions were:

- Had the number or type of lex Maria cases reported to the NBHW by health care providers changed during the period?
- Had the number or type of lex Maria cases forwarded to the MRB by the NBHW changed since the reorganization in 1991?
- Were clinical department heads reported to a greater extent in 1993 than in 1989?

MATERIALS AND METHODS

The study sample consisted of the total number of lex Maria cases reported by health care providers to the NBHW during the years 1989 and 1993, and the number of cases forwarded from this state authority to the MRB during these same two years. The reports were classified by type of activity, type of error, type of professional involved in the event, and whether sanctions were suggested by means of forwarding the reports to the MRB. In order to establish whether there had been any change from 1989 to 1993, a systematic review of every case was conducted to determine whether an individual who was reported to the MRB was the staff member who had performed the medical error.

During the study period from 1989 to 1993, three regulatory changes took place which affected the analysis. First, responsibility for the care of the elderly and services for the disabled was transferred from the county councils to the municipalities in 1992. A second change was that from 1991 and onwards, suicides in the psychiatric sector were not to be reported as lex Maria cases unless they were judged to be preventable. In addition, reports from dentistry and pharmacy were included as lex Maria cases starting in 1991.

RESULTS

Lex Maria cases reported to the NBHW

In 1989, 242 cases were reported to the NBHW compared to 1,348 cases in 1993, excluding psychiatry, dentistry and pharmacy (Table 1). There were 724 cases reported from the municipalities in 1993, which was 54 % of the total number. Excluding this group, there were 242 reports in 1989 and 624 in 1993 from hospitals and the primary health care sector (excluding psychiatry). In the subgroup ‘hospitals and primary health care’, 83% (n = 202) of the cases came from hospitals in 1989 and 84% (n = 529) of the cases in 1993.

Table 1 Type and number of lex Maria cases reported to the NBHW in 1989 and 1993

Type of cases	1989	1993
	n (%)	%
From hospitals and primary health care		
Drug error	38 (16)	145 (23)
Diagnostics	33 (14)	98 (16)
Surgery	36 (15)	125 (20)
Anesthesiology	11 (5)	22 (4)
Obstetrics	9 (4)	14 (2)
Other treatment	79 (33)	200 (32)
No code	36 (15)	20 (3)
Subtotal (hospital and primary health care)	*242 (100)*	*624 (100)*
From the municipalities		
Drug errors	-	521 (72)
Accidental falls	-	100 (14)
Other	-	103 (14)
Subtotal (municipalities)		*724 (100)*
Total	242	1348

Including cases reported to the NBHW from psychiatry, dentistry and pharmacy, a total of 694 cases were reported in 1989 and a total of 1477 cases in 1993.

Cases due to drug errors was the category that increased most, both numerically and percentage-wise, comprising 49% (666 of 1,348) of the total number. Of cases reported by municipalities, drug errors represented 72% of the total number. Another group in which there was an increase in reported cases is surgery, where there was an increase from 15 to 20%. The study data also shows that only 4% of the total number of reported cases in 1993 came from the category anesthesiology.

Lex Maria cases forwarded by the NBHW to the MRB for disciplinary action

The numbers of cases forwarded to the MRB has varied during 1989-1993 between 52 to 81 cases (Table 2). However, since the number of cases reported to the NBHW had increased in 1993, the proportion forwarded for disciplinary review has decreased. Of the total number of lex Maria cases reported to the NBHW during 1989, 35% were forwarded to the MRB, whereas only 5% were forwarded in 1993.

Table 2 The yearly distribution of number of cases forwarded for disciplinary action to the MRB by the NBHW according to type of errors.

Type of cases	1989 % (n = 66)	1990 % (n = 81)	1991 % (n = 52)	1992 % (n = 71)	1993 % (n = 69)
Drug errors	55	58	25	15	17
Diagnostics	12	12	17	30	28
Surgery	20	10	23	17	26
Anesthesiology	3	5	4	8	4
Obstetrics	4	4	10	14	4
Other treatments	6	11	21	15	20

The authority has drastically changed its policy on drug errors (Table 2). In 1989, drug errors comprised 55% of all cases forwarded for disciplinary review. The corresponding proportion in 1993 was only 17%, despite the fact that drug errors still constituted the dominant category of cases reported to the NBHW (Table 1). Most of the 36 drug errors forwarded to the MRB in 1989 were due to insufficient of control resulting in the wrong drug or the wrong dose. The 12 cases in 1993 mainly had other causes and more

serious consequences, and only three cases were due to an incorrect dose. Another obvious change is the proportion of diagnostic cases, which increased from 12% in 1989 to 28% in 1993.

Staff categories reported to the MRB

There was also a change in the categories of staff reported to the MRB by the NBHW (Table 3). During 1989, 35% of the total of 85 individuals reported were medical doctors, whereas in 1993, 73% of the total of 80 individuals reported were doctors. The percentage of nurses reported decreased from 53% in 1989 to 21% in 1993.

Table 3 The yearly distribution of number of individuals in each staff category reported to the MRB by the NBHW for disciplinary action

Staff categories reported to the MRB*	1989	1990	1991	1992	1993
	% (n=85)	% (n=99)	% (n=56)	% (n=79)	% (n=80)
Doctors	35	37	57	75	73
Nurses	53	44	30	18	21
Others	12	18	13	8	6

**The number of individuals in each staff category is numerically greater than the number of reported cases. This is because several persons can be involved in a particular case.*

Analysis of each case (Table 4) showed that in 1993 it was still generally the case that an individual was reported and not department heads. In implementing the new policy, one intention was to examine an event in a broader perspective than before, which would include the increased importance of organizational factors. In 1989, 78% (62 of 79) of the individuals reported could be categorised as those who 'performed the error'. The corresponding figure in 1993 was 91% (69 of 76). Only a few individuals categorised as

Table 4 Number of persons reported to the MRB by the NBHW categorized with respect to the type of error.

Probable cause	Performed the error		Directly contributed to the error		Indirectly responsible for the activity (management)	
	1989	1993	1989	1993	1989	1993
Diverged from routines; no control performed	43	17	8	-	-	-
Inadequate routines, regulations; insufficient organization	5	12	1	2	7	3
Other factors	14	40	1	2	-	-
Total	62	69	10	4	7	3

There was insufficient information about six of the persons reported in 1989, and four in 1993.

DISCUSSION

The aim of this study was to analyze whether the policy of the NBHW for handling lex Maria cases has influenced the reporting of medical errors by the health care sector. Data presented in this study showed that the number of reported lex Maria cases increased from 242 cases in 1989 to 1,348 cases in 1993. A large proportion of the new cases in 1993 came from the municipalities, comprising 54% (n = 724) of the total number of cases (1,348) (Table 1). The large number of lex Maria cases reported resulted in extensive debate focusing on the quality of care given by the municipalities. Some of the cases were associated with

the new structure and organization, but it is not very likely that this change was responsible for the entire increase in cases reported.

It is important to keep certain circumstances related to the regulatory changes in mind with respect to the results. The regulation was changed in 1992, and responsibility for the care of the elderly was transferred from the county councils to the municipalities. At that time a new category of staff was given the responsibility to report lex Maria cases to the NBHW. Before 1992, clinical department heads at the hospitals were generally responsible for selecting cases reported by the health care staff to be forwarded to the NBHW. When the municipalities took over responsibility for the elderly, a chief nurse was given this responsibility. These chief nurses had new functions, and they were informed about the significance of reporting lex Maria cases to the NBHW. Another factor was that, in 1993 from an organizational point of view, patients in the elderly care sector were physically closer to the person whose responsibility it was to report the event. It is important to note that prior to 1992, such patients belonged to the category "hospitals" or "primary health care." The lex Maria responsibility of the clinical department head was much wider, comprising all areas.

Even excluding the cases from the municipalities, there has been an increase in the number of lex Maria cases. It seems reasonable to believe that this increase could be due to the intensive information campaign in connection with the reorganization of the NBHW in 1991. The information stressed that the reporting system was important regarding future preventive initiatives and improved feedback from reported cases, and that employees with organizational responsibilities for routines and procedures would have greater accountability than earlier.

One of the issues taken up in the present report concerned whether the number or type of cases reported to the NBHW that were forwarded to the MRB had changed during the period. Major changes took place, indicating that some policy modifications had occurred at the NBHW during the period. The proportion of cases reported to the NBHW that were forwarded for disciplinary review to the MRB decreased from 31% in 1989 to 5% in 1993. Excluding cases from the municipalities, this proportion decreased to 11% in 1993.

The type of cases the NBHW forwards to the MRB changed during the period. The authority drastically changed its policy regarding drug errors, and these cases were forwarded to a lesser extent than earlier, decreasing from 55% to 17%. For the category of diagnostics there was also a change, although in the opposite direction, from 12% to 28%. These changes influenced the structure of the staff categories that were reported. In 1989, 35% of all individuals whose cases were forwarded to the MRB for disciplinary review were doctors, and 53% nurses. In 1993, 73% of all lex Maria cases reported to the MRB were doctors and only 21% nurses.

It appears as if the intention of the reorganization, which was to include organizational factors to a larger extent than earlier in the review of reported medical errors, has not been fulfilled. Individuals below the management level continued to be reported for disciplinary review in 1993, although the number of medical doctors increased and the number of nurses decreased. The problem of differentiating between an individual and his or her dependence on the organizational structure can be exemplified by drug errors, a major category. A likely explanation is that these kinds of adverse events are rather easy to discover. In addition, the final error is in most cases performed by a single individual who is, in many cases, at a lower level in the medical hierarchy. It may be more difficult to review an adverse event at a higher level, including possible failures at the management level. Rosenthal (1994) describes informal mechanisms regarding doctors, and discusses 'colleague problems' including the protecting of one another.

The results of this study imply that the new policy has had a positive effect in increasing the number of reported medical errors. Different studies have tried to estimate the extent of medical errors, and there is a growing openness in discussing and confessing these problems as well as how the risks to patients can be reduced. The aim of this study is not to estimate the number of patient injuries caused by medical treatment. Nevertheless, the underreporting of lex Maria cases is of interest. When these results are compared with those of other studies, it is reasonable to believe that there is substantial underreporting. The Harvard Medical Practice Study showed that adverse events occurred in 3.7% of cases (Brennan et al., 1991). In a later study in the US, the proportion of adverse events was estimated at 11%, with 42.5% preventable (Bates et al., 1995). The Quality Australian Health Care Study revealed that 16.6% of admissions were associated with adverse events and 51% of the adverse events were judged to be

preventable (Wilson et al., 1996). Another indicator of the magnitude of patient injuries is the Patient Insurance System. In 1993 there were 6,398 cases reported, and in 1998 there were 8,823. Complaints from patients to the MRB increased from 2,000 cases in 1993 to 3,107 cases in 1998. Lex Maria reports have decreased from 1,348 in 1993 to 1,133 in 1998.

Although these results cannot be compared with the number of lex Maria cases reported due to different definitions of adverse events, they are indicators of the magnitude of the problem and suggest that underreporting exists in Sweden. It is important to keep the terminology in mind when referring to reported lex Maria cases. A reported case does not necessarily mean that someone has been negligent; it may have resulted from circumstances that could not have been avoided.

One essential requirement for reducing medical errors is a safety culture in which health care providers, independent of level or position, dare to talk about and also report medical errors (Leape, 1994; Wu et al., 1991). Bogner (1994) discusses the blame trap, and that blaming leads to ineffective counter-measures. Furthermore, reporting may also cause a colleague or a subordinate to receive a warning or a reprimand, or even to lose his/her license. The lex Maria regulation established that the overall purpose of reporting medical errors is prevention. This is difficult due to the fact that, along with its preventive duties, the authority is also obligated to report serious errors to the MRB. This dual role may result in the tendency to underreport, which in turn may make preventive measures more difficult to achieve.

There are several reasons for examining patients' injuries that are caused by medical treatment. One of the most important issues is to obtain information about primary causes in order to develop activities that can prevent recurrences of similar errors (Vincent, Audley and Ennis, 1993; Leape, 1994; Reason, 1997). An additional reason is that these events are not only traumatic for the patients and their relatives, but also for the health care staff that have been involved in the events (Hilfiker, 1984; Christensen et al., 1992; Bogner, 1994). Medical errors are also of concern in the area of occupational health (Sundström-Frisk, 1994; Baldwin, Dodd and Wrate, 1997).

The national Risk Data Base could provide an important base for regulations and recommendations as well as for future medical supervision. However, knowledge about the magnitude and type of patient injuries is an important base for the prevention strategy at the NBHW. Handling lex Maria cases takes considerable resources which may be used ineffectively if cases reported as lex Maria cases do not reflect reality.

Rasmussen (1997) discusses the need to direct attention to aggressive and competitive environments that have been related to several severe accidents in the industrial sector. Reports from several accidents such as at Bhopal, Zeebrugge and Chernobyl, demonstrate this (Perrow, 1984). It seems that Rasmussen's arguments are pertinent to the health care sector, which has also been subjected to extensive structural changes and economic restrictions.

Supervision of the health care sector in Sweden has undergone change during the last few years, and health care providers now have greater responsibility for self-monitoring. The state authority now monitors to a greater extent the way in which health care providers monitor their own activities. This increases the demand for intrinsic control of the activity. Since 1997 all medical services are obligated to have their own local reporting system for adverse events, but their duty to report lex Maria cases to the NBHW still remains.

Results presented in this study estimate that the number of reported lex Maria cases has increased dramatically during the years 1989 to 1993. It is clear that the state authority's manner of handling lex Maria cases has changed during the period. But it also seems that there is a large underreporting of lex Maria cases. One of the major problems with the Swedish lex Maria system still remains, since the NBHW is obligated to report to the MRB. In spite of the fact that lex Maria is regulated by law, and health care providers have the duty to report medical errors, this is dependent on the willingness to report medical errors to the NBHW. The question can be posed as to whether the present manner of handling lex Maria really contributes to improved patient safety. It is problematic to have a self-reporting system run by an authority that is obligated to forward reports for disciplinary action.

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